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House Committee on Oversight and Government Reform
"Safe and Affordable Biotech Drugs – The Need for a Generic Pathway"
Monday, March 26, 2007

Good morning Chairman Waxman, Ranking Member Davis and Members of the Oversight and Government Reform Committee. I am delighted to have the opportunity to testify before your Committee. The focus of my discussion will be the role of small innovator biotechnology companies in the current debate regarding the development of a regulatory pathway for approving biogeneric drugs.

I currently serve as the Chief Executive Officer of Insmed Incorporated. Insmed is a small biotechnology company focused on the development and commercialization of drugs for the treatment of metabolic and endocrine disorders where there are clear unmet medical needs. We received FDA approval for our lead product IPLEX at the end of 2005. IPLEX is a biologic, which is approved for the treatment of children suffering from a rare growth disorder. We are continuing to develop IPLEX for several major medical illnesses such as myotonic muscular dystrophy and medical complications associated with HIV infection.

I am here today to talk about biogeneric drug development and the regulatory path forward. I believe our experience with IPLEX is very illustrative of the scientific and technical issues confronting biogeneric drug developers, issues such as comparability testing and the nature and extent of clinical trials needed to support characterization of a generic biologic. Our experience tells us that these issues can be addressed using a sound, readily available scientific approach.

Insmed has developed significant intellectual capital focused towards protein characterization and purification. We have invested in building the facilities required to manufacture quality proteins. The biogenerics business is a business in which we would like to specialize. The combination of our proprietary protein platform with a biogeneric protein platform meets our goal to sustain innovation along with the ability to provide safe and affordable drugs to address a growing economic issue.
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It is my belief that there are a number of my colleagues in similar size companies that are also interested in providing the scientific expertise to meet the challenges of producing biogenerics. I believe that I am representing the interests of many smaller biotechnology companies and large contract manufacturing companies. I believe H.R.1038 provides for a fair balance between rewarding innovation and creating a timely approval pathway and

commercialization of biogenerics in the marketplace. Passing H.R.1038 would be a positive step for the biotech industry and continue to fuel the cycle of innovation.

As Chief Executive Officer of a small biotechnology company I hope my testimony will provide a different perspective on this important issue and bring to light some of the important reasons H.R.1038 is the correct model to create a robust, competitive and innovative biopharmaceutical marketplace.

IPLEX is a recombinant protein product, in fact it is a combination of two different recombinant protein molecules. It is a relatively large molecule, larger than insulin, growth hormone, the interferons and epogen and certainly no less complex in its structural characteristics. As a new drug, along with the demonstration of safety and efficacy in the target population, structural characterization of the protein and the development of quality manufacturing processes was our central focus during the development of the product. During the course of development we modified the manufacturing process several times. We changed cell lines, purification procedures, raw material sources and, on more than one occasion the facilities. At all times, good analytical methodology was the bedrock of our comparability testing to ensure that we produced a consistent, highly purified protein. Analytical methodology to allow structural characterization of proteins has evolved enormously over the years. It is sophisticated and has exquisite sensitivity. For example, we use a battery of sensitive analytical tests, more than 10, one of which is a technique called mass spectroscopy which has such high resolution that we can detect changes as small as a single proton within the molecule. This is not a crude science.

During the development of IPLEX we worked closely with the FDA. They clearly used their discretion to decide what tests we needed to perform to support our scientific approach as we made changes to our manufacturing processes. Their recommendations were rationale and not onerous. On the occasion that we changed the site of manufacture of the drug, moving our process from a UK facility to our own facility in Colorado, we conducted a simple pharmacokinetic study in human volunteers to establish equivalence of the products after the facility change. We established very quickly, within one month, that the amount of drug in the bloodstream was consistent regardless of where the drug was manufactured.

IPLEX was being developed for use in children and as such both we and the FDA knew that safety at all times was paramount and was certainly never jeopardized. For example, FDA was concerned that immnunogenicity of the product could vary as we changed the process. We established surveillance procedures to address this issue and we continue today to monitor for signs of immunogenicity.

I have only given you a very brief overview of the type of scientific and technical issues we had to address in the development of IPLEX. However, these issues are at the heart of what a biogeneric manufacturer would confront. The science has reached a level of sophistication to make this endeavour entirely possible, all we need now is the regulatory go ahead.

The proposal introduced by Chairman Waxman is extremely appealing as a next step in stimulating competition in order to address an ever growing economic problem facing our healthcare system. Based on our company's experience with the FDA during the approval process of IPLEX, I am confident that the Waxman legislation is based on sound science and progressive insight into where the market should be in the coming years. Thank you again for this unique and important opportunity to share my experience and views. I look forward to your questions.